IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *Ex rel.* CATHLEEN FORNEY Plaintiffs, vs. MEDTRONIC, INC., Defendant.	Case No. 5:15-cv-6264-EGS ORAL ARGUMENT REQUESTED

DEFENDANT MEDTRONIC, INC.'S BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT DUE TO PUBLIC DISCLOSURE BAR

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PRELIMINARY STATEMENT

This case is ripe for summary judgment. Discovery to date has made clear that Ms. Forney has no standing under the False Claims Act (FCA) to pursue her claims. In the interest of justice, Medtronic asks the Court to halt discovery before the parties incur significant additional unnecessary expense and grant summary judgment to Medtronic.

A relator's right to pursue FCA claims on behalf of the United States is circumscribed by the FCA's public disclosure bar, which bars a relator from pursuing claims when substantially the same allegations have been publicly disclosed unless the relator qualifies as an "original source" under the statute. Relator Cathleen Forney lacks standing under this bar. It is undisputable that Ms. Forney's theories in this case were publicly disclosed long before she put pen to paper for either her original or her amended complaints. Nor did Ms. Forney provide information to the United States that was independent of or materially added to the prior public disclosures. As a result, Medtronic is entitled to summary judgment on all counts of Ms. Forney's amended complaint.

Medtronic has moved for summary judgment on this issue now, rather than waiting until the March 2018 scheduled deadline for summary judgment, because the public disclosure bar is an issue of standing and, for part of Relator's case, an issue of jurisdiction. Discovery sufficient to evaluate Realtor's standing has been taken, and the undisputed record makes clear that she has no standing. Under these circumstances, Medtronic respectfully requests that the court stay further discovery and resolve this motion so that the "just, speedy, and inexpensive" resolution of this case may occur. *See* Fed R. Civ. P. 1.

FACTUAL BACKGROUND

I. Relator's Theories of Liability

Relator alleges that Medtronic violated the Anti-Kickback Statute (AKS) and caused the submission of false claims in five ways. First, and primarily, she alleges that Medtronic employees provided technical support after Medtronic's pacemakers and defibrillators were implanted, in the form of "interrogations" or "device checks" at physician's offices and clinics. (SAC ¶¶ 27, 29). Second, she alleges that Medtronic personnel provided technical support to physicians during surgeries in which these were implanted. (SAC ¶ 17). Third, she alleges that Medtronic gave reimbursement guidance to its customers. (SAC ¶ 34). Fourth, she claims that Medtronic provided free "practice management" consulting. (SAC ¶ 37). Finally, she claims that Medtronic personnel performed administrative work for physicians and their office staff. (SAC ¶¶ 32-33).

None of these allegations originated with Relator. As the timeline below illustrates, three years before Relator first brought suit, these allegations began to be publicly disclosed with the unsealing of a series of five *qui tam* complaints. These complaints allege the same theories that Relator is pursuing here, but with detail that she does not include.

II. Prior Public Disclosures and Relator's Complaints

A. The Burns Complaint

On August 19, 2011, a complaint filed by a Medtronic sales representative named John Burns in the United States District Court for the Middle District of Florida was unsealed and became public. (Burns ECF No. 11). In his complaint, Burns alleged that, as part of scheme dating back to 2000 and continuing to the present, "Medtronic has routinely allowed cardiologists who implant Medtronic pacemakers and defibrillators to have those devices rechecked for free." (Burns Compl. ¶ 28). Burns' theory was that these free device checks,

which were also allegedly provided by Boston Scientific and St. Jude Medical, constituted remuneration under the AKS because they gave physicians the opportunity to submit claims for reimbursement for work they did not do. (Burns Compl. ¶ 28).

B. The Onwezen Complaint

On December 2, 2011, an FCA complaint filed by Kathy Onwezen and two co-relators in the United States District Court for the District of Minnesota was unsealed and became public. (Onwezen ECF No. 53). The Onwezen complaint alleged that Medtronic's technical support for its implanted pacemakers and defibrillators violated the AKS. (Onwezen Compl. ¶ 8). Among other things, they alleged that this kickback scheme, which they claimed dated back to at least 1995 and continued through the present, involved Medtronic field personnel assisting physicians during device implantation procedures and conducting post-implantation interrogations and device checks. (Onwezen Compl. ¶¶ 3, 54). The Relators alleged that Medtronic used these technical support practices to induce sales, telling "doctors and hospitals that if they used a Medtronic device, they will not have to be involved in any of the patient's follow-up care," because Medtronic would do it for them. (Onwezen Compl. at ¶ 68).

The Onwezen complaint further alleged that Medtronic personnel systematically handled all aspects of the remote monitoring and billing processes for its customers, and handled "all of the paper-work related to billing for implant patients." (Onwezen Compl. at ¶¶ 78-82, 95-104).

C. The Stokes Complaint

On October 24, 2013, a complaint filed in the United States District Court for the District of Columbia by Ben Stokes, a former manager for healthcare economics for Medtronic, was unsealed and became public. (Stokes ECF No. 18). The Stokes complaint alleged that Medtronic, Boston Scientific, and St. Jude Medical provided post-implant technical support in such a way that they prematurely drained the batteries of their cardiac rhythm devices. (Stokes

Compl. ¶ 4). Stokes' complaint describes the post-implant technical support allegedly provided by Medtronic and its competitors in detail, claiming among other things that "device interrogations and reprogramming are customarily performed by the device representatives themselves, without direct physician supervision or review." (Stokes Compl. ¶ 63).

D. The Schroeder Complaint

On May 27, 2014, the United States District Court for the Eastern District of California unsealed and thereby publicly disclosed a complaint filed by Adolfo Schroeder, a former business development manager for Medtronic's cardiac rhythm business. (Schroeder ECF No. 75). Among other things, Schroeder alleged in his complaint that Medtronic paid in-kind kickbacks in the form of reimbursement advice and business consulting services, beginning in at least 2004 and continuing to the present. (Schroeder Compl. ¶¶ 51, 73-75, 81).

E. The John Doe Complaint

On June 20, 2016, the United States District Court for the District of New Jersey unsealed and thereby publicly disclosed a complaint filed by two anonymous relators, both identified as practicing cardiologists. (Doe ECF No. 8). The John Doe complaint alleged that "for several decades through the present," Medtronic, Boston Scientific, St. Jude Medical, and Biotronik had engaged in a nationwide scheme of paying kickbacks in the form of "free technical services in connection with the necessary health monitoring of cardiac patients" with implantable cardiac rhythm devices. (Doe Compl. ¶ 3). The complaint described device interrogations in detail, alleging that the average patient has between two and four interrogations performed per year, and that interrogations are usually performed by device manufacturer personnel for free. (Doe Compl. ¶¶ 70-77). The relators also alleged two instances in which Medtronic representatives, one in New Jersey and another in Philadelphia, provided specific reimbursement advice. (Doe Compl. ¶¶ 110-15, 212-17).

F. The Forney Complaints

Against this backdrop of extensive, repeated public disclosures, Relator filed her original complaint in this case on November 20, 2015. (ECF No. 1). The Burns, Onwezen, Stokes, and Schroeder complaints had all already been publicly disclosed by that time. Relator filed her first amended complaint on April 3, 2017. (ECF No. 17). The Doe complaint was publicly disclosed between the filing of Relator's original and first amended complaints. Following dismissal of the first amended complaint, Relator filed her second amended complaint (SAC) on July 3, 2017. (ECF No. 40).

STANDARD OF REVIEW

Summary judgment is appropriate when the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Ebbert v. DaimlerChrysler Corp.*, 319 F.3d 103, 108 (3d Cir. 2003). "[W]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *United States ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 683 (E.D. Pa. 2009) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d. 538 (1986) (internal quotation marks omitted). The moving party carries the initial burden of demonstrating the absence of any genuine issues of material fact, and "[o]nce the moving party has produced evidence in support of summary judgment, the nonmovant must go beyond the allegations set forth . . . and . . . demonstrate[] there is a genuine issue of fact for trial." *United States ex rel. Showell v. Philadelphia AFL, CIO Hosp. Ass'n*, CIV. A. 98-1916, 2000 WL 424274, at *1 (E.D. Pa. Apr. 18, 2000), *aff'd sub nom. United States ex rel. Showell v. Philadelphia AFL, CIO Hosp. Ass'n*, 275 F.3d 38 (3d Cir. 2001). Summary judgment must be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's

case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

ARGUMENT

The "core purpose" of the *qui tam* provisions of the FCA is to encourage individuals with personal knowledge of a concealed fraud to bring suit and thereby notify the government of the alleged wrongdoing. *See, e.g.*, *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 210 (1st Cir. 2016). Consistent with this purpose, the FCA's public disclosure bar strikes a balance between incentivizing whistleblowers to come forward on the one hand, and blocking suits by "opportunistic late-comers who add nothing to the exposure of the fraud" on the other. *See United States ex rel. Tahlor v. AHS Hosp. Corp.*, No. 2:08-CV-02042 WJM, 2013 WL 5913627, at *11 (D.N.J. Oct. 31, 2013).

The pertinent provisions of the public disclosure bar read, "The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party . . . [unless] the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2012). Absent opposition by the government, the public disclosure bar thus mandates the dismissal of an action if: (1) the public disclosure appears in certain enumerated sources, including federal hearings to which the United States or its agent was a party; (2) the public disclosure contains "substantially the same allegations or transactions" as alleged in relator's complaint; and (3) the relator is not an "original source."

Relator filed her original complaint on November 20, 2015. (ECF No. 1). The statute of limitations for the FCA is six years, 31 U.S.C. § 3731(b), so the time period at issue in this case could extend back to November 20, 2009. The current version of the public disclosure bar came

into effect on March 23, 2010, with the enactment of the Patient Protection and Affordable Care Act (PPACA). The pre-PPACA version of the public disclosure bar deprived courts of jurisdiction if: (1) there was a public disclosure of an allegation or clear inference of fraud, (2) in certain enumerated sources, including civil hearings, (3) the relator's complaint was "based upon" the public disclosure; and (4) the relator was not an original source. 31 U.S.C. § 3730(e)(4)(A) (2006); *United States ex rel. Zizic v. Q2Adminstrators, LLC*, 728 F.3d 228, 233, 239 (3d Cir 2013). In cases where the alleged conduct straddles the PPACA amendment, courts in the Third Circuit apply the pre-PPACA statute to alleged "pre-amendment conduct and the amended [statute] to later conduct." *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 69 F.Supp.3d 416, 423 (D. Del. 2014), *rev'd on other grounds*, 812 F.3d 294 (3d Cir. 2015).

I. Relator's Device Check Theory Is Barred by the Public Disclosure Bar.

A. Relator's Device Check Allegations are "Substantially the Same" as the Prior Public Disclosures.

The theory that Medtronic provided free device checks and other post-implantation product support as an inducement was publicly disclosed in four separate *qui tam* complaints, all of which were unsealed before Relator filed the SAC, and three of which were unsealed before she commenced this action by filing her original complaint under seal. As with Relator's theory here, the central theory in three of these complaints was that free device checks constitute impermissible remuneration under the AKS. (Onwezen Compl. ¶ 8; Burns Compl. ¶¶ 28, 36, 38; Doe Compl. ¶¶ 3, 77); (*see also* Burns ECF No. 5 at 2) ("Medtronic . . . allow[s] cardiologists who implant [its] pacemaker and defibrillator devices [to] have those devices routinely checked by the defendant['s] sales personnel at no charge to the cardiologists."). All of these prior public disclosures alleged that Medtronic provided a high volume of free, post-implant product support.

(Burns Compl. ¶¶ 19, 27, 37; Doe Compl. ¶¶ 74-76, 81-83; Onwezen Compl. ¶¶ 68-77; Stokes Compl. ¶¶ 15, 53, n.1). These prior complaints all allege continuing conduct. (Onwezen Compl. ¶¶ 3, 54; Burns Compl. ¶ 28; Stokes Compl. ¶ 63; Doe Compl. ¶ 3). They also disclosed that this conduct was nationwide. (Burns Compl. ¶ 30; Onwezen ¶¶ 14, 16; Doe Compl. ¶¶ 3, 110-15); *see also* (Burns ECF No 8. at 2).

Not only do these earlier complaints allege the same theory as to defendant's conduct, they also allege the same evidence when pleading Medtronic's intent. The Schroeder complaint introduces the concept that without free services, there was little to distinguish Medtronic's products from the competition (Schroeder Compl. ¶ 7)—a sentiment Relator repeated when she called these devices "off the shelf commodities," (SAC ¶ 47). The Burns complaint cites the exact same passage of the AdvaMed Code as Relator cites when arguing that Medtronic knew or should have known that providing free product support was impermissible. (Burns ¶ 24; SAC ¶ 46). Like Relator, Burns also referenced the obscure companion manual to the AdvaMed Code that Medtronic and certain other cardiac rhythm manufacturers published in 2009. (Burns Compl. Ex. 4; SAC ¶ 40). Finally, Relator's inapposite and somewhat odd effort to plead Medtronic's earlier corporate integrity agreement as evidence of Medtronic's knowledge here was also preceded by the same maneuver in the Onwezen complaint, nearly four years before Relator's complaint. (Onwezen Compl. ¶ 6; SAC ¶ 41).

Since these prior disclosures were all made in unsealed *qui tam* complaints, they qualify as public disclosures under the statute. *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 333 (3d Cir. 2005); *United States ex rel. Denis v. Medco Health Sols., Inc.*, Civ. No. 11-684-RGA, 2017 WL 4838410, at *5 (D. Del. Oct. 26, 2017). Given the greater detail in these prior complaints, it is clear that the statutory test – whether the SAC is "substantially the same" – is

met. Indeed, the SAC is not only "substantially the same," it is a pale imitation of the considerable public disclosures that preceded it.

B. Relator is Not an Original Source of the Device Check Allegations under the Post-PPACA Public Disclosure Bar.

Under the current version of the public disclosure bar, there are two ways for a relator to qualify as an original source. First, a relator is an original source if, "prior to a public disclosure," she "has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based." 31 U.S.C. § 3730(e)(4)(B)(i) (2012). Second, a relator is an original source if she "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and if she "voluntarily provided the information to the Government before filing an action under this section." *Id.* at § 3730(e)(4)(B)(ii). Forney meets neither standard.

The first standard – disclosing the information underpinning her complaint to the government before the first public disclosure – is not even arguably applicable here. The first public disclosure occurred in August 2011, when the Burns complaint was unsealed, back when Relator was still working for Medtronic and more than four years before she filed her first complaint. Relator stated at her deposition that she did not provide information to the government until approximately June 2015. (Ex. L, Forney Tr. at 153:8 – 154:20).

Relator also fails to qualify as an original source under the second prong, since none of the information in her complaint or that she provided to the government before filing suit "materially adds to the publicly disclosed information." 31 U.S.C. § 3730(e)(4)(B)(ii) (2012). Information is "material" if it is "significant, influential, or relevant." *Moore*, 812 F.3d at 306. As the Supreme Court recently held, information is material when it is of sufficient importance to influence the behavior of the recipient. *See Universal Health Servs., Inc. v. United States ex*

rel. Escobar, 136 S.Ct. 1989, 2004 (2016). "So to 'materially add' to the publicly disclosed allegation or transaction of fraud, a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *Moore*, 812 F.3d at 306. A relator's addition must be "distinct from what was publicly disclosed" and it must add "in a significant way to the essential factual background: 'the who, what, when, where, and how of the events at issue.'" *Id.* at 307. Logically, "[a]s the level of detail in public disclosures increases, the universe of potentially material additions shrinks." *Winkelman*, 827 F.3d at 211; *see also Zizic*, 728 F.3d at 238 (holding that additional details such as the identity of the particular employee responsible for a publicly disclosed fraud was "too insubstantial" to qualify the relator as an original source under the pre-PPACA original source exception).

"When viewed against the backdrop of information that cumulatively was disclosed" before Relator filed her operative complaint, Relator does not add "significant unknown details to the essential factual background of the alleged fraud." *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, No. 2:12-cv-1600, 2016 WL 1255294 (W.D. Pa. Mar. 31, 2016). The earlier *qui tam* complaints alleged that Medtronic provided device checks and other forms of post-implant product support for free to physicians and hospitals across the country for decades, as a form of inducement. Relator alleges that these practices also occurred in her Eastern Pennsylvania district. (SAC ¶¶ 49-50).[1] "Offering specific examples of that conduct

[1] In her deposition, Relator stated that she provided approximately 10 or 12 documents to the government in June 2015. (Ex. L, Forney Tr. at 153:8 – 154:20). She further stated that to the best of her knowledge all of the documents she provided to the government were cited in her complaints. (Ex. L, Forney Tr. 256:4-9). Accordingly, the SAC, as her most detailed complaint, summarizes all of the relevant information that Relator provided to the government before filing suit.

Medtronic asked Relator in an interrogatory and at her deposition to convey the substance of any communications she had with the government. (Ex. N, Relator's Interrogatory Responses, at 1-2; Ex. L, Forney Tr. 156:2-12). Medtronic also requested the production of all documents provided to the government. (Ex. M, Relator's RFP Responses, at 1). Each time, Relator's counsel objected, asserting various privileges and protections. (Ex. N, Relator's Interrogatory Responses, at 2; Ex. L, Forney Tr. 156:13 – 165:6; Ex. M, Relator's RFP Responses, at 2). Medtronic advised Relator's counsel at Ms. Forney's deposition that it had identified public disclosures that

does not provide any significant new information where the underlying conduct already has been publicly disclosed." *Winkelman*, 827 F.3d at 212. Accordingly, Relator does not qualify as an original source as to these allegations, and her complaint should be dismissed with prejudice as a result.

C. Relator is Not an Original Source of the Device Check Allegations under the Pre-PPACA Public Disclosure Bar.

Under the pre-PPACA formulation of the original source exception, an original source is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filling an action under this section . . . ." 31 U.S.C. § 3730(e)(2)(B). "'Direct knowledge' is knowledge obtained without any 'intervening agency, instrumentality, or influence: immediate." *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 520 (3d Cir. 2007) (quoting *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991)). "'Independent knowledge' is knowledge that does not depend on public disclosures." *Id.* (quoting *Stinson*, 944 F.2d at 1160).

Relator cannot meet her burden of proving that she has direct and independent knowledge of any false claims submitted before March 23, 2010. A relator does not qualify as an original source by having direct and independent knowledge of a supposed kickback scheme, because the FCA does not prohibit kickback schemes; it prohibits false or fraudulent claims and false records or statements material thereto. *See United States ex rel. Schumann v. AstraZeneca Pharms. L.P.*, 769 F.3d 837, 846 (3d Cir. 2014) ("[A] relator was not an original source because it did not have

bar Ms. Forney's claims, including specifically the Burns complaint that was unsealed in 2011. To the extent Ms. Forney would rely on any disclosure she made to the government to support an argument that she qualifies as an original source, that information is not privileged or otherwise protected from disclosure. Regardless, since any such disclosure is not currently part of the record, it cannot be used to meet Relator's burden of proving that she qualifies as an original source.

direct and independent knowledge of the most critical element of its claims, *viz.*, that the defendant had made the alleged misrepresentations to the government." (quoting *United States ex rel. Mistick PBT v. Housing Auth. of the City of Pitt.*, 186 F.3d 376, 388 (3d Cir. 1999))) (internal quotation marks and modifications omitted). To qualify as an original source under the pre-PPACA public disclosure bar, Relator would need to have direct and independent knowledge of false claims predating March 23, 2010. *See id.* at 847 (citing *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 336 & n. 11 (3d Cir. 2005). Relator does not allege the specifics as to any false claims that were submitted before that date; the only supposed claims she referenced were from late 2011. (SAC ¶ 49).[2] At best, Relator has a "mere suspicion that there must be a false or fraudulent claim lurking around here somewhere," which "simply does not carry [her] burden of proving that [she] is entitled to original source status." *Schumann*, 769 F.3d at 847 (quoting *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 353 (4th Cir. 2009)).

II. Relator's Implant Surgery Theory Is Barred.

Relator's complaint primarily concerns post-implantation device checks, but she also claims that product support during implant surgeries constitutes remuneration under the AKS. The facts underpinning this theory, however, were also publicly disclosed.

Back in 2008, the Onwezen complaint alleged that it was "common practice" for Medtronic personnel to attend implant surgeries "to answer any questions that may arise about the device, provide guidance about installation and program the device." (Onwezen Compl. ¶ 54). Onwezen elaborated that Medtronic personnel might also "conduct[] an 'interrogation' of

[2] During her deposition, Relator stated that paragraph 49 of the SAC was based on information contained in Google Calendar records and emails that she accessed and printed after her employment with Medtronic ended. (Ex. L, Forney Tr. 233:4 – 240:4). She does not have personal knowledge as to whether these procedures or those listed in paragraph 50 of the SAC were performed as scheduled. (*See* Ex. L, Forney Tr. 244:8 – 245:18). She also does not have personal knowledge as to whether any of the associated patients were Medicare beneficiaries, much less whether any claims were actually submitted. (*See* Ex. L, Forney Tr. 243:13 – 244:7). Relator is therefore not an original source of the assertion in the SAC that claims were submitted for all these procedures.

the device, performing device systems checks and programming the patient's identifying information data onto a telemetric (or programming) wand." (Onwezen Compl. ¶ 54). Afterward, the Medtronic employee would prepare an "Implant Data Report" and a "Surgical-op Report." (Onwezen Compl. ¶ 55). The Stokes complaint concurred that Medtronic personnel provided these technical services during implant surgeries. (Stokes Compl. ¶ 56).

The foregoing is significantly more detail than Relator alleged in her complaint or presumably provided to the government. All Relator said in her complaint was that Medtronic provided "free surgical support" and "free surgical staffing assistance." (SAC ¶¶ 47-49). These statements merely summarize in general, conclusory terms the far more detailed allegations that had already been publicly disclosed. Relator's statements add no detail whatsoever – let alone distinct and material information – and thus do not help her clear the public disclosure bar. *See Moore*, 812 F.3d at 306.

III. Relator's Practice Management Theory Is Barred.

Relator alleged in the complaint that Medtronic taught its employees "how to provide free consulting services" and offered "free consulting on all sorts of practice management topics." (SAC ¶ 37). To the extent that these perfunctory allegations can be said to be a theory of liability, it is a theory that is "substantially the same" as a prior public disclosure. Specifically, the Schroeder complaint alleged that Medtronic promoted a "'turn-key' heart failure clinic business solution" that enabled physicians to run profitable heart failure clinics using Medtronic's pre-printed forms and templates. (Schroeder Compl. ¶ 81).

Nor does Relator qualify as an original source as to these allegations. Relator's reference to "practice management topics" provides the skeletal outline of a theory of remuneration, while Schroeder's more detailed allegations put meat on those bones. Here again, Relator's allegation is fully encompassed by, and less specific than, a prior public disclosure If this is an attempt to

get over the public disclosure bar, Relator is going in the wrong direction. *Moore*, 812 F.3d at 306; *Winkelman*, 827 F.3d at 211.

IV. Relator's Administrative Work Theory Is Barred.

Relator provides two examples of situations in which Medtronic personnel did what might be regarded as administrative work for customers. First, she alleges, with no supporting details, that she wrote a spreadsheet to help a hospital track remote monitoring patients. (SAC ¶ 32). Second, she says two unidentified clinical specialists entered data for two hospitals. (SAC ¶ 33).

Both of these types of allegations were publicly disclosed in the Onwezen complaint. Indeed, the Onwezen complaint that Medtronic personnel systematically handled all aspects of the remote monitoring and billing processes for its customers. (Onwezen Compl. ¶¶ 78-82, 95-104). Regarding remote monitoring, Onwezen alleged that since 2002 Medtronic personnel had used the CareLink remote monitoring system "to handle almost all aspects of the patient's medical follow-up care, without a licensed physician or staff member present." (*Id.*at ¶ 100). Similarly, Onwezen alleged that Medtronic representatives handled "all of the paper-work related to billing for implant patients." (Onwezen ¶ 79).

In light of Onwezen's sweeping allegation of systematic misconduct involving remote monitoring, no reasonable person would consider Relator's claim that she once completed a remote-monitoring spreadsheet to be a material addition. *See Moore*, 812 F.3d at 306. ("[A] relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality.") Likewise, Relator's claim that she knows of two sales representatives who entered data for hospitals is but part and parcel of Onwezen's broad allegations. To the extent that Relator's allegations regarding administrative work could

constitute an independent theory of liability on their own, Relator does not qualify as an original source of these allegations and they are barred.

V. Relator's Reimbursement Guidance Theory Is Barred.

In one paragraph of the SAC, Relator alleged that Medtronic taught health care providers how to "maximize[e]" their reimbursement payments through a program called PRO/CV. (SAC ¶ 34). This scant allegation from Relator is "substantially the same" as the allegations in the publicly disclosed *qui tam* complaints. Like Relator, Schroeder alleged that Medtronic's reimbursement guidance and consulting constituted in-kind remuneration under the AKS. (Schroeder Compl. ¶ 51). He also alleged that the objective of such guidance was to teach health care providers how "to maximize Medicaid and Medicare billing." (*Id.* at ¶ 72). He then went far beyond the SAC, describing billing seminars, pre-filing billing review, detailed billing instructions, and specific business plans for teaching health care providers how to maximize their profits from reimbursement. (*Id.* at ¶¶ 72-76). The scope of these programs was articulated by Stokes, who alleged that he personally provided reimbursement advice in 300 hospitals across 40 states. (Stokes Compl. ¶ 59). The Doe and Onwezen complaints provided additional examples of situations in which Medtronic personnel provided advice on how to maximize reimbursement. (Doe Compl. ¶¶ 110-15, 212-17; Onwezen Compl. ¶¶ 75, 87-88).

Relator's only contribution to this significant body of publicly disclosed allegations was to identify the brand name—PROC/CV—that would later be given to an alleged reimbursement consulting initiative. Such trivia does not add "in a significant way to the essential factual background." *Moore*, 812, F.3d at 307. Accordingly, Relator does not qualify as an original source of these allegations, and they are barred.

CONCLUSION

For all of the foregoing reasons, this case should dismissed, and judgment should be entered for Medtronic on all counts.

Respectfully submitted,

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